# Validation of flow convergence region method in the assessment of carotid artery stenoses during color-flow duplex studies

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*Purpose:* The flow convergence region (FCR) method (also known as the proximal isovelocity surface area method) is currently used in echocardiography to evaluate the flow through cardiac valves and septal defects. The FCR method is based on the characteristic alterations in flow dynamics that occur proximal to a stenotic orifice. Blood converges uniformly and radially towards an orifice that is small relative to the section of the vessel and forms concentric isovelocity hemispheric shells where velocity progressively increases and flow remains laminar. The purpose of the article is to validate the use of this principle in the detection and assessment of carotid stenoses in the course of color-flow duplex studies.
*Methods:* In this prospective study, 80 patients affected by unilateral or bilateral carotid artery stenoses were evaluated for the presence of the FCR from February 1997 to March 1999. The results were compared with digital subtraction angiography.
*Results:* Color-flow duplex diagnosis of carotid artery stenoses of 70% or more was confirmed in 100% of the carotid artery stenoses (40/40 patients) with angiography. The FCR was detected in 72.2% (13/18) of carotid arteries affected by stenoses greater than 80%, in 54.4% (12/22) of carotid arteries affected by stenoses 70% to 80%, and in 13.6% (6/44) of carotid arteries affected by stenoses 50% to 69% ($P$ <.001). In 5% of cases (2/40 of stenoses) the FCR was the only detectable sign of carotid stenosis.
*Conclusion:* Our data suggest that a routine search for FCR in the course of color-flow duplex study of carotid arteries may further improve the reliability of this examination in the detection of carotid artery stenoses, particularly in the presence of heavily calcified lesions. (J Vasc Surg 2000;31:484-9.)

The purpose of this study was to evaluate the accuracy of flow convergence region (FCR), also known as proximal isovelocity surface area method, in the assessment of carotid artery stenoses. The evaluation of FCR has been successfully used in echocardiography for many years. The FCR method is based on the characteristic alterations in flow dynamics that occur proximal to a stenotic orifice. The flow converges uniformly and radially towards an orifice that is small, relative to the section of the vessel, and forms concentric isovelocity hemispheric shells in which velocity progressively increases and flow remains laminar. In fact, according to conservation of mass, flow rate across any isovelocity surface is equal to orifice flow. The cross-sectional slices of these hemispheric volumes appear at color-flow duplex (CFD) scanning as one or more areas of alternating blue and red, delineated by interfaces in which velocity acts as an alias at a given Nyqvist limit, proximal to the stenosis and converging towards it (Fig 1). This method has proved to be reliable and operator independent in the assessment of the flow through a stenotic or regurgitant valve or through atrial and ventricular septal defects.[1,2] Even so, it is influenced by other factors, such as the shape of the stenotic orifice.[3-5]

In the vascular laboratory, the CFD evaluation of carotid artery stenoses is based on quantitative and qualitative elements, which have been widely investigated. An increasing sensitivity and specificity of CFD in the detection of carotid artery disease and

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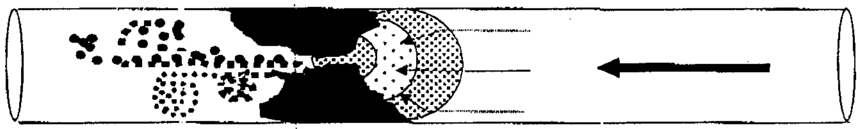

Fig 1. The FCR in close proximity of a stenosis. The *arrow* indicates the direction of the flow.

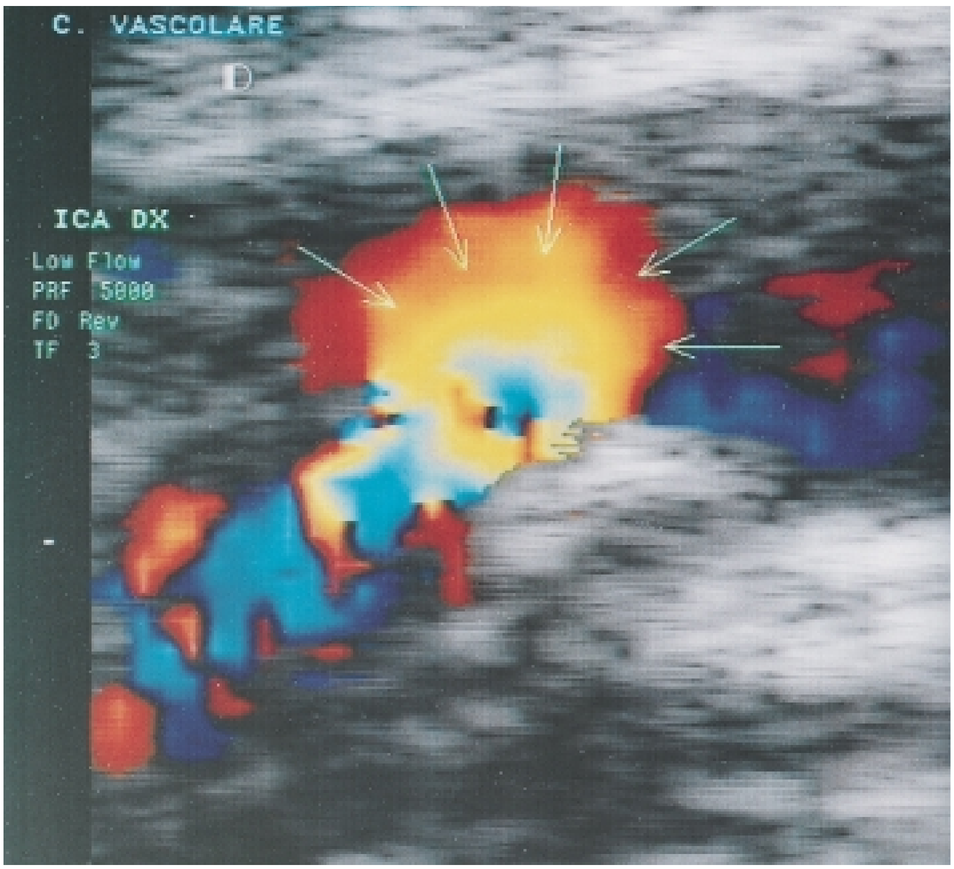


Fig 2. A typical carotid artery stenosis with FCR (*arrows*) and poststenotic turbulent flow.

the identification of plaque morphologic features have been reported in different series,[6-9] but reliable results often still depend on an experienced operator. For this reason, it is useful to set new objective methods to reduce interobserver variations. The FCR principle, to our knowledge, has never been applied to the CFD evaluation of carotid artery stenoses. In fact, the quantitative assessment of the flow-through carotid artery stenoses has little clinical significance, even if the hydrodynamic principles of the methods are potentially applicable to any restrictive orifice.[10] For vascular purposes, the examiner will just have to look for the presence of FCR because it will indirectly reveal the close proximity of a stenotic orifice. Unfortunately, as an alternative to the simple evaluation of FCR, the evaluation of the velocity at the entry point of the stenosis is technically demanding or impossible. Furthermore, with an orifice of finite size, there is a progressive flattering of the isovelocity concentric shells as they approach the orifice.[11] The appearance of FCR will therefore become the hallmark of a carotid artery stenosis (Fig 2).

## MATERIAL AND METHODS

**Type of the study and sample size.** This was a prospective, nonrandomized trial. We assumed that stenoses of 70% or more would have produced an increase of 50% to 75% in the frequency of detection of FCR, compared with stenoses of less than 70%. For a test with $\alpha = 0.05$ (type I error, false positive results) and $\beta = 0.1$ (type II error, false negative results), the number of carotid artery stenoses to test would have been more than 60.[12]

Within stenoses of 70% or more, we assumed that stenoses of more than 80% would have produced an increase of 35% in the frequency of detection of FCR, compared with stenoses of 70% to 80%. For $\alpha = 0.05$ and $\beta = 0.4$, the number was more than 40. Therefore two groups of cases were identified: group A, carotid artery stenoses of 50% to 69%, and group B, carotid artery stenoses of 70% or more. Both groups were examined with CFD from February 1, 1997, to March 1, 1999.

The quantitative definition of a CFD diagnosis of the carotid artery stenosis of 50% to 69% was a peak systolic velocity (PSV) of more than 120 cm / sec and less than 210 cm / sec. The quantitative definition of a CFD diagnosis of the carotid artery stenosis of 70% to 80% was a PSV of 210 cm / sec or more plus an end-diastolic velocity of more than 70 cm / sec. The quantitative definition of a CFD diagnosis of carotid artery stenosis of more than 80% was a PSV of more than 250 cm / sec plus an end-diastolic velocity of more than 100 cm / sec.

These criteria came from a meta-analysis of the criteria of different authors.[13-21] Thus we supposed 89% to 94% sensitivity and 83% to 86% specificity for our measurements, according to the Blakeley study.[22]

**Definition of carotid artery stenosis with digital subtraction angiography.** Digital subtraction angiography (DSA) was performed with biplanar arch aortography and selective carotid artery catheterization; diameter reduction was calculated with the European Carotid Surgery Trial (ECST) method. In the North American symptomatic carotid endarterectomy trial (NASCET), the tightest residual lumen ($d$) is measured and then compared with the far distal internal carotid artery ($n$), whereas in ECST it is compared with an imaginary outline ($n$) of the carotid artery bulb. In both cases, the applied formula is $1 - (d/n) \times 100$. Generally, the stenotic areas calculated by the NASCET and ECST methods show excellent agreement with the data from the duplex method and from the planimetry of the angiographic data. According to some authors, both the NASCET and ECST methods underestimate the planimetric measurements of surgical specimens and the duplex evaluation.[23] For a given arteriogram, ECST measurement tends to overestimate and NASCET tends to underestimate the stenosis. From a clinical point of view, NASCET and ECST measurements of stenoses are equally good predictors of an ipsilateral stroke.[24] Angiogram evaluation was performed with precision electronic calipers on magnified views.

**Examiner.** The single examiner had 6 years of experience and had conducted more than 8000 examinations with the CFDs.

**Eligibility.** The exclusion criteria were (1) restenosis, (2) a CFD diagnosis of stenosis less than 50%, (3) stenoses at the carotid artery bifurcation that involved both external and internal carotid arteries, and (4) stenoses that involved proximal vessels (common carotid artery, brachiocephalic artery). Inclusion criteria were (1) contralateral occlusion or stenosis, (2) occlusion or stenosis of vertebral arteries, (3) ulcerated plaques, and (4) carotid artery bifurcation that was anatomically higher than normal.

**Devices used.** A 590 Asynchronous scanner (Esaote Biomedica SpA, Genova, Italy) with a 7.5-MHz linear array probe and a Gateway VST Master Series (Diasonics Ultrasound Inc, Milpitas, Calif) with linear array probes of 5 to 10 MHz were used. Both scanners were analog and used frequency domain techniques.

**CFD settings.** The pulse repetition frequency (PRF) was usually set at 2500 to 4000 kHz, (usually 3000 kHz). With these settings, the Nyqvist limit varied from 14 cm / sec for a PRF of 2500 kHz to 38 cm / sec for a PRF of 4000 kHz. The color box was steered when necessary to show the FCR properly. Angular correction was used for the proper evaluation of the flow velocity to obtain accurate measurements. The angle of the ultrasonic beam was always $\theta$ of less than 70 degrees. The stenoses were always evaluated in the anteroposterior and posteromedial projections. The FCR was exclusively evaluated during the systolic flow, with any diastolic pattern ignored. Systole was defined with simultaneous electrocardiography or with consideration for the concurrence of the colorimetric pattern of FCR with the peak systolic flow on the Doppler trace in triplex mode.

**Statistical analysis.** Nonparametric tests were applied; a comparison of the groups was performed with $\chi^2$ analysis. Group B was further examined with $\chi^2$ analysis. Confidence intervals of 95% (95% CI) for the difference were specified. In patients with FCR as the only sign of carotid artery stenosis, the


**Fig 3.** Another aspect of the FCR: the heavily calcified plaque obstructs the view of post-stenotic flow. FRC is the only hallmark of a close high-grade stenosis of internal carotid artery.

**Table I.** Presence of FCR within groups with different percentages of carotid artery stenoses

| *Group* | *Stenoses with FCR (%)* | $\chi^2$ | P *value* | *Degrees of freedom* | *95% CI* |
|---|---|---|---|---|---|
| A (50%-69%) | 13.6 (6/44) | 21.48 | .0000035 | 1 | 0.28-0.69 |
| B (≥ 70%) | 62.5 (25/40) | | | | |

95% CI per proportion was applied. Differences were considered statistically significant when two-tailed tests yielded a *P* value of less than .0001.

Between February 1997 and March 1999, 84 CFD-diagnosed carotid artery stenoses of more than 50% (76 monolateral, 4 bilateral) that matched the aforementioned criteria were evaluated to detect the presence of the FCR. Stenoses of 50% to 69% were assigned to group A, and stenoses of 70% or more were assigned to group B. Within group B, stenoses were further divided in two subgroups: stenoses of 70% to 80% and stenoses of more than 80%. All the patients with a CFD diagnosis of carotid artery stenosis of 70% or more underwent DSA. A CFD diagnosis of stenosis of 50% to 69% was further confirmed with DSA in patients with the FCR.

## RESULTS

The occurrence of FCR varied markedly according to the degree of stenosis (Table I). Within group A, FCR was usually present at PRF of 2500 kHz or lower, disappearing for higher PRFs. Within group B, FCR was usually present at PRFs of 3000 to 4000 kHz. The presence of FCR increased with the increase of the stenosis, even if this tendency had little statistical relevance (Table II).

**Table II.** Presence of FCR in the subgroups within group B

| *Group* | *Stenoses with FCR (%)* | $\chi 2$ | P *value* | *Degrees of freedom* | *95% CI* |
|---|---|---|---|---|---|
| B (70%-80%) | 54.5 (12/22) | 1.32 | .25 | 1 | –0.12-0.48 |
| B (> 80%) | 72.2 (13/18) | | | | |

Even though there was minimal discrepancy between CFD and DSA in the quantification of the stenoses (as confirmed by larger multicenter studies, DSA tends to underestimate the stenoses if compared with CFD), CFD diagnosis of carotid artery stenosis of more than 70% was confirmed in 100% of the cases with DSA. Among these, the FCR was the only sign of presumed carotid artery stenosis in 5% of group B (2/40 stenoses; 95% CI, –1.8% to 11.8%). These patients underwent DSA exclusively on the basis of the presence of FCR. In the first case, the carotid artery bifurcation was very high, and the poststenotic flow was therefore impossible to observe; in the second case, an annular, heavily calcified plaque completely hid the stenosis and the poststenotic tract (Fig 3).

The detection of FCR in these series, matching group A versus group B, was 75% accurate, with 62.5% sensitivity and 86.3% specificity. The negative predictive value of the test was 71.6%; its positive predictive value was 80.6%. False positive results were 19.3%; false negative results were 28.3%.

## DISCUSSION

The purpose of the study was to validate the FCR method in the assessment of carotid artery stenoses during CFD examination.

The data collected suggest that this method offers accuracy and specificity that is considerably lower than those data typically reported with traditional criteria. Thus it may improve the reliability of CFD in association with standard velocity measurements and three-dimensional evaluation of the plaque morphologic features.[25,26] However, in peculiar situations (ie, anatomically high carotid artery bifurcations), it might be impossible to observe poststenotic turbulent flow. Similarly, heavily calcified annular plaques may hide high-grade stenoses. In these cases, stenosis could be unmasked by the evaluation of FCR, which may become the only sign of the narrowing of a vessel in close proximity.

Notwithstanding the small amount of false positive results, it appears that stenoses of less than 70% seldom show FRC with PRF set at 2500 kHz or higher, even optimizing the steering of the color box and other color settings. Furthermore, in our experience, FCR never appears with PRF set at 2500 kHz or higher in less than 50% of stenoses. This apparent behavior did not undergo statistical evaluation because of the lack of data concerning the different PRFs set by the examiner in every single case.

Within group B, there was not a significant difference between stenoses of 70% to 80% and stenoses of more than 80%. This is of little clinical significance because a carotid artery stenosis of more than 70% is still hemodynamically important, and surgical correction is usually recommended.[27-29]

The drawbacks of the study are the relatively small number of patients, the lack of data concerning the ability by other examiners to reproduce the test, and the lack of data concerning the different PRFs set in every case.

To our knowledge, nobody has ever applied this method in the evaluation of carotid artery stenoses, even though cardiologists have shown the importance of FCR in echocardiography. An increasing number of vascular surgeons consider CFD the gold standard in the evaluation of carotid artery stenosis before surgery.[30-32] In fact, CFD has been shown to be reliable and to improve the cost-effectiveness of carotid artery endarterectomy.[33,34] Thus every effort to increase the accuracy of CFD in the vascular laboratory should be made, and the evaluation of FCR could become a routine habit for all examiners because it is quick and easy to perform.

Whether this method is useful, reliable, and widely acceptable in clinical practice still remains to be confirmed both by larger and multicenter studies and by the use of modern time domain technique scanners.

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